

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: BENICAR (OLMESARTAN)	*	MDL 2606
PRODUCTS LIABILITY LITIGATION	*	
	*	
THIS DOCUMENT RELATES TO	*	JUDGE ROBERT B. KUGLER
ALL CASES	*	
	*	MAG. JUDGE JOEL SCHNEIDER

**PROPOSED JOINT AGENDA AND REPORT
FOR 18 NOVEMBER 2015 STATUS CONFERENCE:**

1. Report on Docket.

There were 1,128 complaints on file with the clerk's office as of November 9, 2015, and 1,055 complaints have been served on at least one U.S. Defendant. .

2. State Court Litigation.

There are currently 66 cases pending in the New Jersey MCL. The next case management conference will be on November 30, 2015.

3. Core Deficiencies in Plaintiff Fact Sheets.

DEFENDANTS' POSITION:

As of November 13, 2015, 346 PFS have been received and 179 have been reviewed for core deficiencies. Of the 179 which have been reviewed, 50 PFSs – approximately 28 percent – do not have medical records showing that the plaintiff had sprue-like enteropathy or a similar condition and/or do not have pharmacy records showing proof that the plaintiff took an olmesartan medicine.

70 core deficiency letters have been sent out as of November 13, 2015. The following chart lists 12 cases where 10 days have passed since the deficiency letters have been sent out but Defendants have not received a response to same:

No.	Case Caption	PFS Core Deficiency Letter Sent	Plaintiff Counsel Firm	MDL Case No.
1	Dubose, Claude and Sherrea Dubose v. Daiichi Sankyo, Inc., et al.	09/17/15	Golomb & Honik PC	1:15-cv-04780
2	Freeman, Anthony v. Daiichi Sankyo, Inc., et al.	09/17/15	Golomb & Honik PC	1:15-cv-04990
3	Moore, Shirley M. and Arthur Moore v. Daiichi Sankyo, Inc., et al.	09/17/15	McEwen Law Firm Ltd.	1:15-cv-03294
4	Bujol-Brown, Bernadette v. Daiichi Sankyo, Inc., et al.	10/2/15	Irpino Law Firm	1:15-cv-2567
5	Sandrovich, James v. Daiichi Sankyo, Inc., et al.	10/2/15	Levin Papantonio Thomas Mitchell Rafferty & Proctor, P.A.	1:15-cv-03829
6	Bradshaw, Gail v. Daiichi Sankyo, Inc., et al.	10/14/15	Sizemore Law Firm	1:15-cv-05009
7	Seymour, Mable v. Daiichi Sankyo, Inc., et al.	10/15/15	Sizemore Law Firm	1:15-cv-05003
8	Johnson, Donna v. Daiichi Sankyo, Inc., et al.	10/26/15	Sizemore Law Firm	1:15-cv-05005
9	McFan, Angel v. Daiichi Sankyo, Inc., et al.	10/26/15	Sizemore Law Firm	1:15-cv-05004
10	Woodard, Robert v. Daiichi Sankyo, Inc., et al.	10/26/15	Golomb Honik, P.C.	1:15-cv-04970
11	Walker, Doshia and Calvin Walker v. Daiichi Sankyo, Inc., et al.	10/27/15	Golomb Honik, P.C.	1:15-cv-04921
12	Walker, William v. Daiichi Sankyo, Inc., et al.	10/27/15	Golomb Honik, P.C.	1:15-cv-05439

Local Rule 37.1 requires the parties to meet and confer to resolve any discovery dispute and to certify that “the moving party has conferred with the opposing party in a good faith effort to resolve by agreement the issues raised by the [motion] without the intervention of the Court

and that the parties have been unable to reach agreement”. That has not occurred here as to the issues raised by the plaintiffs below. The parties had their first discussion about this issue at the end of the day on Friday, but Plaintiffs’ counsel Steve Resnick (whose firm has five of the above cases) was unprepared to discuss the specific facts of any of the cases. Whether a given PFS is “core deficient” must be discussed in the context of that specific PFS. As such, and because Plaintiffs have not complied with Local Rule 37.1, this issue is not ripe for discussion and should be deferred.

PLAINTIFFS’ POSITION:

Defendants have adopted a practice of asserting that an appropriately completed PFS is non-compliant. The most prevalent alleged deficiencies claimed by Defendants include the failure of a plaintiff to identify the date of diagnosis of sprue-like enteropathy or identity of the diagnosing physician – in cases where no treating physician diagnosed sprue-like enteropathy. As the Court is well aware, there are many plaintiffs who displayed symptoms that are clinically consistent with the severe gastrointestinal symptoms caused by the olmesartan drugs, but they did not have an endoscopic biopsy performed to definitively demonstrate the pathology caused by olmesartan. Plaintiffs in those cases will prove the existence of the gastrointestinal injuries caused by the olmesartan drugs based on the clinical picture. Therefore, the responses are appropriate in those cases. Another prevalent claim of deficiency is the Defendants’ subjective evaluation of the severity of the gastrointestinal symptoms suffered by a plaintiff, and/or determination that the gastrointestinal symptoms documented are not severe enough. Since it is not Defendants’ right to determine whether the injuries are severe enough, the deficiencies should be withdrawn.

As Plaintiffs' Counsel indicated at the last meeting with the Court, Defendants' interpretation of the injuries that Plaintiffs must allege to remain in this MDL is extremely narrow and unreasonable. Despite the Court's instruction on this issue, Defendants continue to claim "deficiencies" in the completed PFSs based on their narrow view.

4. Overdue Plaintiff Fact Sheets

DEFENDANTS' POSITION:

As of November 12, 2015, 32 PFS are overdue. The following chart identifies those PFS that are more than one week overdue:

No.	Case Caption	Complaint First Service Date	Plaintiff Counsel Firm	PFS Due Date
1	Waggoner, Addie Louise v. Daiichi Sankyo, Inc., et al.	04/29/15	Mazie Slater Katz & Freeman LLC	07/28/15
2	Ambler, Suzanne and Ambler, Richard v. Daiichi Sankyo, Inc., et al.	05/26/15	Yale & Baumgarten LLP	08/24/15
3	Byrd, Reginald v. Daiichi Sankyo, Inc., et al.	06/15/15	Golomb Honik, P.C.	09/14/15
4	Belser, McKindle v. Daiichi Sankyo, Inc., et al.	06/17/15	Mazie Slater Katz & Freeman LLC	09/15/15
5	Block, Norman v. Daiichi Sankyo, Inc., et al.	06/17/15	Levin Papantonio Thomas Mitchell Rafferty & Proctor, P.A.	09/15/15
6	Leggett, Cindy Sue v. Daiichi Sankyo, Inc., et al.	06/17/15	Mazie Slater Katz & Freeman LLC	09/15/15
7	Lee, Lisa Kay and Lavern Lee v. Daiichi Sankyo, Inc., et al.	06/29/15	Duncan, Green, Brown & Langeness, P.C.	09/28/15
8	Moore, Mary v. Daiichi Sankyo, Inc., et al.	06/30/15	Schlichter, Bogard and Denton	09/28/15
9	Rodriguez, Herbert and Sheila Rodriguez v. Daiichi Sankyo, Inc., et al.	06/30/15	Mazie Slater Katz & Freeman LLC	09/28/15
10	Misiaszek, Rosie Lee v. Daiichi Sankyo, Inc., et al.	07/01/15	Mazie Slater Katz & Freeman LLC	09/29/15
11	Radke, Patricia Ann v. Daiichi Sankyo, Inc., et al.	07/01/15	Mazie Slater Katz & Freeman LLC	09/29/15

No.	Case Caption	Complaint First Service Date	Plaintiff Counsel Firm	PFS Due Date
12	Sorrow, Sarah v. Daiichi Sankyo, Inc., et al.	07/01/15	Mazie Slater Katz & Freeman LLC	09/29/15
13	Brown, Carol and Ralph Brown v. Daiichi Sankyo, Inc., et al.	07/02/15	Robins, Kaplan, Miller & Ciresi L.L.P	09/30/15
14	Calloway, Ronald v. Daiichi Sankyo, Inc., et al.	07/02/15	Orlando Firm, P.C.	09/30/15
15	McGruder, Charlene and Darius McGruder v. Daiichi Sankyo, Inc., et al.	07/07/15	Golomb Honik, P.C.	10/05/15
16	Sitaula, Vonderlita and Ram Sitaula v. Daiichi Sankyo, Inc., et al.	07/07/15	Golomb Honik, P.C.	10/05/15
17	Griffin, Zachary and Lavonne Griffin v. Daiichi Sankyo, Inc., et al.	07/09/15	Spangenberg Shibley & Liber, LLP	10/07/15
18	Baltimore, Frank v. Daiichi Sankyo, Inc., et al.	07/13/15	Sizemore Law Firm	10/12/15
19	Chavis, Cecile v. Daiichi Sankyo, Inc., et al.	07/13/15	Sizemore Law Firm	10/12/15
20	Cunningham, Carmen v. Daiichi Sankyo, Inc., et al.	07/13/15	Sizemore Law Firm	10/12/15
21	Harrington, Polly v. Daiichi Sankyo, Inc., et al.	07/13/15	Sizemore Law Firm	10/12/15
22	Hudson, Linda and Darryl Hudson v. Daiichi Sankyo, Inc., et al.	07/13/15	Sizemore Law Firm	10/12/15
23	Zeno, Barbara v. Daiichi Sankyo, Inc., et al.	07/13/15	Sizemore Law Firm	10/12/15
24	Barnes, Anthony v. Daiichi Sankyo, Inc., et al.	07/15/15	Golomb & Honik, P.C.	10/13/15
25	Cole, James P. v. Daiichi Sankyo, Inc., et al.	07/15/15	Wagstaff & Cartmell LLP	10/13/15
26	Gilmore, Alan v. Daiichi Sankyo, Inc., et al.	07/15/15	Wagstaff & Cartmell LLP	10/13/15
27	McKay, Gregory v. Daiichi Sankyo, Inc., et al.	07/15/15	Golomb Honik, P.C.	10/13/15
28	Mobilia, Daniel v. Daiichi Sankyo, Inc., et al.	07/15/15	Wagstaff & Cartmell LLP	10/13/15

No.	Case Caption	Complaint First Service Date	Plaintiff Counsel Firm	PFS Due Date
29	Wythe, Marilyn v. Daiichi Sankyo, Inc., et al.	07/17/15	Golomb Honik, P.C.	10/15/15
30	Mitchell, Lucy v. Daiichi Sankyo, Inc., et al.	07/24/15	GoldenbergLaw, PLLC	10/22/15
31	DeLee, Edward Glenn and Resa Birch v. Daiichi Sankyo, Inc., et al.	07/27/15	McGlynn, Glisson, & Mouton	10/26/15
32	Johnson, Jeanette (TN) v. Daiichi Sankyo, Inc., et al.	07/31/15	Gilreath & Associates	10/29/15

Plaintiffs are responsible to know when their PFS are due, and they three months to identify the deadline and prepare the PFS. See Judge Kugler's rulings at the 6/30/15 Case Management Conference, 38:5 to 11. Defendants oppose permitting Plaintiffs to "red shirt" their cases by dismissing them without prejudice and waiting to see what happens. Rule 11 (b) requires that there be a factual basis for a case, stating "By presenting to the court a pleading, written motion, or other paper...an attorney...certifies that to the best of the person's knowledge, information and belief, formed after an inquiry reasonable under the circumstances...(3) the factual contentions have evidentiary support or, if specifically so identified, will likely have evidentiary support after a reasonable opportunity for further investigation or discovery." Fed. R. Civ. P. 11(b)(3). In this litigation, plaintiffs allege and are therefore required to provide records supporting a diagnosis of "serious gastrointestinal injury, including sprue-like enteropathy, lymphocytic colitis, microscopic colitis and collagenous colitis." In re Benicar (olmesartan Products Liability Litigation, MDL No. 2606, Dkt. 121, 2015 U.S. Dist. LEXIS 44047 (J.P.M.L. 4/3/15). If they cannot do so, the complaint was filed in violation of Rule 11(b) and should be dismissed with prejudice.

PLAINTIFFS' POSITION:

Plaintiffs have not received deficiency notices in each of these cases, and will investigate the status of each. In the event a plaintiff is slow to respond to his or her counsel, or has indicated reticence to proceed at this time, Plaintiffs seek leave to dismiss those cases without prejudice, predicated on a requirement that the case be refiled in the MDL if that is to occur. Plaintiffs have discussed this proposal with defense counsel, and Defendants indicated an unwillingness to agree to this procedure, which will avoid the filing of motions and thus save the Court's staff from having to process the motions, in what is an easily addressed situation.

Plaintiffs request that dismissal of a case for failure to timely serve a PFS be without prejudice in the initial instance, with a mechanism and time frame set out to provide for cases to be reinstated where a PFS is served, and to allow adequate time for Plaintiffs' counsel to provide notice to the plaintiff and directions as to the remaining time frame and consequences of failing to comply, in each instance. Plaintiffs are hopeful that this process can be instituted without accompanying motion practice to promote efficiency and avoid burdening the Court.

5. Discovery To Date

DEFENDANTS' POSITION:

To date, Defendants have produced 8,592,131 pages of documents which include documents in categories and from custodians that Plaintiffs at one point or another have deemed a priority. That number will reach approximately 10 million pages next week. This is in addition to responses to 78 interrogatories, including subparts, on behalf of the Daiichi U.S. and Forest Defendants, and Daiichi Japan; responses to 271 requests for production of documents, including subparts, on behalf of the Daiichi U.S. and Forest Defendants; 197 requests for production of documents, including subparts, on behalf of Daiichi Japan; responses to 156

requests for admissions, on behalf of the Daiichi U.S. and Forest Defendants, and Daiichi Japan; 73 supplementation letters for all defendants combined; 30 ROADMAP requests for production of documents on behalf of the Daiichi U.S. Defendants; collection and review of documents from 231 custodians using 606 search terms, including variations; and responses to hundreds of informal requests, which continue every day. On August 26, 2015, the Daiichi U.S. Defendants served written responses to Plaintiffs' First Request for Production of ROADMAP Study Documents, and offered to produce the study Trial Master File (TMF). In their responses, Defendant specifically stated that "[t]he mechanism of the production remains to be determined." On September 25, 2015, the Daiichi U.S. Defendants produced paper study documents located in the United States.

Following service of their written responses, Defendants learned that the ROADMAP study TMF consists of 3,000 folders in 540 boxes, which is estimated to be more than 1.5 million pages all in paper, and located in Germany. For that volume of documents, collection alone would take 14-16 weeks to complete at a cost of \$1.6 - \$2 million. Under those circumstances, to save time and expense, on October 26, 2015, Defendants offered to make the documents available for Plaintiffs' review in Germany, so that they can review the files and tab for copying what they want. In furtherance of that process, on November 5, 2015, Defendants produced the TMF indices, and now await Plaintiffs' response as to whether and when they would like to review the documents in Germany.

Local Rule 37.1 requires the parties to meet and confer to resolve any discovery dispute and to certify that "the moving party has conferred with the opposing party in a good faith effort to resolve by agreement the issues raised by the [motion] without the intervention of the Court and that the parties have been unable to reach agreement". That has not occurred here as to the

issues raised by the plaintiffs below for the first time mid-Tuesday morning. As such, and because Plaintiffs have not complied with Local Rule 37.1, this issue is not ripe for discussion and should be deferred.

PLAINTIFFS' POSITION:

Plaintiffs agreed to adopt the New Jersey state court discovery in the MDL, based on defense counsel's representations that this would speed discovery. Instead, Defendants have resisted the production of discovery that was requested beginning in June, 2014, and have failed to produce discovery at a steady or robust pace. Defendants have not fully responded to the listed discovery requests. For example, the Court is well aware that the response to the ROADMAP document requests has been scant and Defendants have dug in, in an effort to avoid responding to many of the requests. In apparent violation of the Court's order, the Defendants produced the index to the Trial Master File, failing to produce an index of the overall Clinical Trial, after engaging in a lengthy discussion with the Court and being ordered to do so. Defendants also advised in vague terms that the only documents that **may** be available in electronic form are "study-related correspondence." Aside from the vague, unquantified nature of this unhelpful disclosure, their position that almost nothing is maintained in electronic form continues to defy credibility. For example, are Defendants representing the statistical analyses were performed in pencil on paper? Do they assert that the study grant requests and approvals are not maintained electronically? Are the adverse event and efficacy tables handwritten? Such questions could easily go on and on.

6. Shifting Priorities and On-Going Discovery Requests

DEFENDANTS' POSITION:

Contrary to the Court's clear instruction, Plaintiffs continue to make additional demands for production, resulting in conflicting priorities. Since October 1, 2015, the plaintiffs have

made over 100 individual requests for documents or information. This volume of requests, covering only six weeks, is more discovery than would be deemed reasonably appropriate, and it is but a subset of the on-going and unremitting requests and comes on top of the “macro issue” discovery. On October 22, 2015, Plaintiffs identified 27 custodians they deemed a priority, and Defendants regrouped document production to focus on these custodians. At the October 28, 2015 status conference, Plaintiffs provided Defendants with another list of priorities for production. As instructed by the Court, Defendants confirmed this list with Plaintiffs in a November 4, 2015 letter, and changed their production schedule and processes to focus on Plaintiffs’ priorities. Then, on November 5, 2015, Plaintiffs provided a list of 18 initial deponents for whom they want full custodial files prior to depositions. Six of these 18 deponents do not overlap with the 27 custodians previously deemed a priority. Meaning that at plaintiffs’ request, on October 22, the defense put the custodial files for these six people aside, only to be told two weeks later that the files should be expedited. Requiring Defendants to continually shift gears causes unnecessary delays in the production process, and Defendants should be given adequate and reasonable time to produce the documents. The Court should call a halt to the constant flow of informal discovery requests.

PLAINTIFFS’ POSITION:

Plaintiffs have requested discovery at a reasonable pace and in a reasonable manner. As set forth above, Plaintiffs agreed to adopt the New Jersey state court discovery, yet Defendants have objected to many of those requests and when Plaintiffs seek to prioritize production of documents and information requested in New Jersey in June, 2014, Defendants disingenuously claim these requests are new. Plaintiffs are in compliance with the Court’s directions and Orders. The ultimate problem is Defendants’ obstruction of discovery, inefficiencies in the

production process, delays occasioned by relevancy reviews and other steps taken for Defendants' benefit.

Despite Plaintiffs' multiple efforts to prioritize discovery and witnesses, Defendants continue, in what appears to be a calculated strategy, to insist that they cannot produce custodial and other documents within the timeframe mandated by the Court. In light of this, and in a further effort to prioritize deponents, Plaintiffs renew their request for 30(b)(6) depositions.

7. Deposition Protocol

Pursuant to the Court's instruction, on November 11, 2015, the parties filed simultaneous letter briefs concerning the following issues regarding the Deposition Protocol and will be prepared to argue these issues at the conference:

1. Whether Daiichi Sankyo Co., Ltd. employees can be compelled to appear in the United States for depositions;
2. Whether depositions of Daiichi Sankyo Co., Ltd. employees can be conducted via video-conference;
3. Whether defendants should be required to give advance notice if Daiichi Sankyo Co., Ltd. employees who are prospective deponents will be in the United States so that they can be subpoenaed for depositions in the United States; and
4. Whether two cameras will be permitted during videotaped depositions.

8. Deposition Schedule

DEFENDANTS' POSITION:

The commencement date set by the Court is premature and compliance is not possible. On November 5, 2015, Plaintiffs provided an initial list of 18 deponents for depositions to begin on January 18, 2016. Four of these witnesses were not on Plaintiffs' October 22 "priority" list

for document production. The custodial files for these 18 deponents total over 2,686,618 documents, which we expect to equal twenty to thirty million pages of documents, assuming a modest 10 pages per document, but it could be more. Due to the volume of documents, Defendants will be unable to produce the custodial files for these initial deponents prior to January 18, 2016. Even if Defendants continue production at a rate of two to four million pages per month, which decreases every time priorities shift or reviewers need to be diverted to other projects, production of all of the custodial files for the 18 deponents to enable depositions to begin in January is not feasible. Defendants submit that depositions should not begin until May 2016 in order to ensure that the custodial files will be produced. Any other result deprives both parties of due process. Each witness should be produced for deposition only once. If depositions begin in January, it will be without full custodial files. Defendants anticipate that plaintiffs will then argue that they are entitled to a second round of depositions of the same witnesses, something which the defendants strongly oppose.

PLAINTIFFS' POSITION:

Plaintiffs continue to be skeptical of Defendants' position regarding the time they need to produce documents. Any difficulties Defendants are having in completing productions on the prioritized documents are of their own doing. Plaintiffs are prepared to abide by the timelines ordered by the Court, but obviously cannot begin depositions without first receiving adequate document production.

9. Bellwether Selection Process

The parties have submitted separate orders for the Bellwether Selection Process. The parties met and conferred on this issue on October 15 and 26, 2015. The parties re-submit their

proposals with this Agenda as were submitted with the Joint Agenda prior to the October 28, 2015 status conference. (Plaintiffs' proposal as Exhibit 1, Defendants' proposal as Exhibit 2).

10. Fact Sheet Deadlines

DEFENDANTS' POSITION:

On Thursday afternoon, November 12, The Defendants requested that the deadline for all Defendant Fact Sheets due between December 18, 2015 and January 4, 2016, shall be extended to January 18, 2016 and offered a reciprocal extension to the Plaintiffs. The Defendants' offices are closed for two weeks during the holidays. The Plaintiffs apparently oppose this request.

PLAINTIFFS' POSITION:

Defendants did not present or discuss this request with Plaintiffs before inserting it into the agenda. Plaintiffs, like Defendants, wish to enjoy the holiday season, and believe that extensions should easily be given and reciprocated on a case by case basis.

11. ROADMAP Production

DEFENDANTS' POSITION:

On August 26, 2015, the Daiichi U.S. Defendants served written responses to Plaintiffs' First Request for Production of ROADMAP Study Documents, and offered to produce the study Trial Master File (TMF). In their responses, Defendant specifically stated that "[t]he mechanism of the production remains to be determined." On September 25, 2015, the Daiichi U.S. Defendants produced paper study documents located in the United States.

Following service of their written responses, Defendants learned that the ROADMAP study TMF consists of 3,000 folders in 540 boxes, which is estimated to be more than 1.5 million pages all in paper, and located in Germany. For that volume of documents, collection alone would take 14-16 weeks to complete at a cost of \$1.6 - \$2 million. Under those circumstances,

to save time and expense, on October 26, 2015, Defendants offered to make the documents available for Plaintiffs' review in Germany, so that they can review the files and tab for copying what they want. In furtherance of that process, on November 5, 2015, Defendants produced the TMF indices, and now await Plaintiffs' response as to whether and when they would like to review the documents in Germany.

Local Rule 37.1 requires the parties to meet and confer to resolve any discovery dispute and to certify that "the moving party has conferred with the opposing party in a good faith effort to resolve by agreement the issues raised by the [motion] without the intervention of the Court and that the parties have been unable to reach agreement". That has not occurred here as to the issues raised by the plaintiffs below. As such, and because Plaintiffs have not complied with Local Rule 37.1, this issue is not ripe for discussion and should be deferred.

PLAINTIFFS' POSITION:

Defendants limited their disclosures to documents contained within the Trial Master File rather than the broader disclosures ordered by the Court. As a result, Plaintiffs request that the Court address this issue.

12. Defendants' Letter to the Court Regarding DFS

DEFENDANTS' POSITION:

Defendants sent a letter to the Court on and have not received a response from Plaintiffs. Once such a response is received, Local Rule 37.1 requires the parties to meet and confer to resolve any discovery dispute and to certify that "the moving party has conferred with the opposing party in a good faith effort to resolve by agreement the issues raised by the [motion] without the intervention of the Court and that the parties have been unable to reach agreement". That has not occurred here as to the issues raised by the plaintiffs below. The parties have not

discussed this issue live. As such, and because Plaintiffs have not complied with Local Rule 37.1, this issue is not ripe for discussion and should be deferred.

PLAINTIFFS' POSITION

Plaintiffs have reviewed Defendants' letter to the Court advising that they cannot comply with their DFS disclosure obligations. Plaintiffs dispute the validity of Defendants' position and intend to submit a letter to the Court in response. Plaintiffs provided defense counsel notice of the intent to respond in writing and asked if Defendants will agree to the submission of the attachments to the letter, including the DOJ subpoena and certain additional documents, which are currently marked confidential by the Defendants. Plaintiffs will be prepared to discuss this issue at the hearing.

Dated: November 17, 2015

Respectfully Submitted,

/s/ Susan M. Sharko

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